10-27-03

AF/B

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:

J. Ronald Wilk

Serial No.: 09/800,360

Filed: March 6, 2001

For: WOUND TREATMENT SOLUTION AND METHOD FOR USING SAME

Group Art Unit: 1616

Examiner: Barbara P. Badio

CERTIFICATE OF EXPRESS MAILING

37 C.F.R. §110

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BRIEF ON APPEAL

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Sir/Madam:

Pursuant to 37 C.F.R. § 1.192, Applicant J. Ronald Wilk files this brief in triplicate in support of his appeal from the final rejection in the Office Action mailed May 29, 2003 in the above-identified patent application. A check in the amount of $165.00 is enclosed as the requisite fee, since the Applicant is a small entity. If this check is inadvertently not enclosed or is insufficient in any respect, the Commissioner is authorized to charge any deficiencies (or credit any overpayments) to Jackson Walker L.L.P., Deposit Account No. 10-0096, Order No. 121944.00001.

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I. REAL PARTY IN INTEREST

The real party in interest in this application and appeal is J. Ronald Wilk, 608 Water Oak Drive, Plano, Texas, 75025, the inventor of the above-identified application.

II. RELATED APPEALS AND INTERFERENCES

Neither the Inventor nor the Inventor's legal representatives know of any other appeal or interference which will directly affect, or be directly affected by, or have a bearing on the Board's decision in this appeal.

III. STATUS OF CLAIMS

Claims 1-22 and 24-42 are the claims on appeal and are set forth fully in Appendix A to this brief. A final rejection of claims 1-22 and 24-42 was mailed on May 29, 2003.

IV. STATUS OF AMENDMENTS

An amendment was filed subsequent to the final rejection of May 29, 2003, to amend the specification of this application to address an objection made by the Examiner for the first time in the Office Action mailed May 29, 2003. This amendment was entered by the Examiner in the advisory action dated September 10, 2003. However, the Examiner denied the request for reconsideration

arguing that the amendment did not place the application in condition for allowance in light of previous rejections made in the final rejection of May 29, 2003.

V. SUMMARY OF THE INVENTION

A. General Background

The solution of the present invention generally comprises cedar leaf oil, zinc oxide ointment, calamine lotion, and an ointment base. In one embodiment, the cedar leaf oil comprises between about 5% and about 10% of the total weight of the solution, the zinc oxide comprises from between about 5% to about 10% of the total weight of the solution, and the calamine lotion comprises from between about 2% to about 10% of the total weight of the solution. In one embodiment, an ointment base, such as petroleum jelly and USB lanolin may then be added to form the remainder of the weight of the solution. (See specification, page 6, paragraph 21.)

Cedar leaf oil, otherwise known as Thuja oil, may be produced through distillation of the leaves of the tree commonly known as the Arbor Vitae. In its pure form, cedar leaf oil may act as a neurotoxin, meaning that its use may cause nerve damage under certain circumstances. However, it has been found that if cedar leaf oil is appropriately diluted, according to the present invention, it may become an excellent topical analgesic, meaning that when applied directly to the skin or other tissue, it may relieve pain locally in the area where applied. (See specification, page 3, paragraph 9.) Once properly diluted and mixed with the other elements of the present invention, the overall

combination creates an unexpected, synergistic effect which simultaneously promotes healing, reduces swelling, removes redness, and encourages fluid removal. (See Declaration of Dr. Wilk, paragraphs 7-10 and Exhibits A-C.) In one embodiment, Vitamin K may also be utilized to promote healing. In this embodiment, Vitamin K comprises between about 1% and about 2% of the total weight of the solution. In a preferred embodiment, the present invention comprises approximately 10% cedar leaf oil by weight, approximately 10% zinc oxide ointment by weight, approximately 10% calamine lotion (medicated) by weight, and approximately 70% ointment base comprising 50% anhydrous USB lanolin with 50% pure petroleum jelly. Artificial food coloring may then be added to tint the solution as desired for commercial purposes. (See specification, page 2, paragraph 6.)

VI. ISSUES

1. Did the Examiner err in rejecting claims 1-42 under the provisions of 35 U.S.C. §103(a) as being unpatentable over Nesbit ('403) in view of Warren et al. ('583)?

VII. GROUPING OF CLAIMS

Claims 1-42 do not stand or fall together, and the grouping of the claims is as follows:

Group I - Claim 1-15;

Group II - Claims 16-30; and

Group III - Claims 31-42.

VIII. THE EXAMINER'S POSITION WITH RESPECT TO THE REFERENCES USED TO REJECT THE CLAIMS

The Examiner rejected claims 1-42 of the present invention under the provisions of 35 U.S.C. §103(a) as being unpatentable over Nesbit ('403) in view of Warren ('583). In citing this rejection, the Examiner states that the Nesbit reference "teaches a topical composition for impregnating a bandage comprising from .5 to 40% weight of zinc oxide for treatment of skin diseases. (See the entire article)." The Examiner further states that the Nesbit reference "teaches the addition of other ingredients such as calamine and preservatives, including antibacterial and antiviral agents (column 1, lines 5-42; column 3, claims 1-3 and 5)."

The Examiner continues by stating "the instant claims differ from the reference by reciting a composition comprising cedar leaf oil. However, cedar leaf oil is a known natural antibacterial active agent as taught by Warren et al. (column 7, lines 1-8)." Thus, the Examiner argues that "it would have been obvious to one having ordinary skill in the art at the time of the invention to make a composition of Nesbit having cedar leaf oil as the antibacterial agent. The motivation to add an antibacterial such as cedar leaf oil is based on the teachings of Nesbit that said addition preserve the composition by removal of any bacteria not removed during sterilization (see column 1, lines 13-20)."

The Examiner addresses the varying ranges provided by the instant claims by arguing that "when the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re: Aller*, 105 U.S.P.Q. 233. Optimization

of the composition taught by Nesbit by variation of the amount of zinc oxide, calamine and antibacterial agent involves routine skill that is within the level of skill of the ordinary artisan in the art, and, thus, the claimed invention is *prima facie* obvious." (See Office Action of November 21, 2001, pages 2-3.)

IX. ARGUMENT

A. Standards for Establishing a *Prima Facie* Case of Obviousness

Three criteria must be established in order to make out a *prima facie* case of obviousness based on a combination of prior art references. First, there must be some suggestion or motivation, either in the references used by the Examiner or in the knowledge generally available to one of ordinary skill in the art, to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference or references, when combined, must teach or suggest all of the claimed limitations. *See* M.P.E.P. § 2143; *see also In re Vaeck,* 947 F.2d 488, 493 (Fed. Cir. 1991). The teaching or suggestion to make the claimed combination must be found in the prior art, not in the applicant's disclosure. *Vaeck*, 947 F.2d. at 493.

The ultimate determination of whether an invention would have been obvious under 35 U.S.C. § 103(a) is a legal conclusion based on underlying findings of fact. *See In re Dembiczak,* 175 F.3d at 998, 50 USPQ2d at 1616 (Fed.Cir.1999). Substantial evidence is something less than the weight of the evidence but more than a mere scintilla of evidence. *See id.* at 1312, 203 F.3d 1305, 53

USPQ2d at 1773 (quoting *Consolidated Edison Co. v. NLRB,* 305 U.S. 197, 229-30, 59 S.Ct. 206, 83 L.Ed. 126 (1938)). In reviewing the record for substantial evidence, the Board must take into account evidence that both justifies and detracts from the factual determinations. *See Universal Camera Corp. v. NLRB,* 340 U.S. 474, 487-88, 71 S.Ct. 456, 95 L.Ed. 456 (1951).

A critical step in analyzing the patentability of claims pursuant to section 103(a) is casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. *See Dembiczak,* 175 F.3d at 999,50 USPQ2d at 1617. Close adherence to this methodology is especially important in cases where the very ease with which the invention can be understood may prompt one "to fall victim to the insidious effect of a hindsight syndrome wherein that which only the invention taught is used against its teacher." *W.L. Gore & Assocs., Inc. v. Garlock, Inc.,* 721 F.2d 1540, 1553, 220 USPQ 303, 313 (Fed.Cir.1983).

Most if not all inventions arise from a combination of old elements. *See In re Rouffet,* 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457 (Fed.Cir.1998). Thus, every element of a claimed invention may often be found in the prior art. *See id.* However, identification in the prior art of each individual part claimed is insufficient to defeat patentability of the whole claimed invention. *See id.* Rather, to establish obviousness based on a combination of the elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant. *See In re Dance,* 160 F.3d 1339, 1343, 48 USPQ2d 1635, 1637 (Fed.Cir.1998); *In re Gordon,* 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed.Cir.1984).

Even when obviousness is based on a single prior art reference, there must be a showing of a suggestion or motivation to modify the teachings of that reference. See *B.F. Goodrich Co. v. Aircraft Braking Sys. Corp.*,72 F.3d 1577, 1582, 37 USPQ2d 1314, 1318 (Fed.Cir.1996).

The motivation, suggestion or teaching may come explicitly from statements in the prior art, the knowledge of one of ordinary skill in the art, or, in some cases the nature of the problem to be solved. See *Dembiczak*, 175 F.3d at 999, 50 USPQ2d at 1617. In addition, the teaching, motivation or suggestion may be implicit from the prior art as a whole, rather than expressly stated in the references. See *WMS Gaming, Inc. v. International Game Tech.*, 184 F.3d 1339, 1355, 51 USPQ2d 1385, 1397 (Fed.Cir.1999). The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art. *See In re Keller,* 642 F.2d 413, 425, 208 USPQ 871, 881 (1981) (and cases cited therein). Whether the Board relies on an express or an implicit showing, it must provide particular findings related thereto. *See Dembiczak,* 175 F.3d at 999, 50 USPQ2d at 1617. Broad conclusory statements standing alone are not "evidence." *Id.*

B. The Examiner Failed to Establish a *Prima Facie* Case of Obviousness

1. The Examiner's rationale for combining the Nesbit and Warren references is flawed.

As noted above, the Examiner relies upon the language of column 1, lines 13-20 of the Nesbit reference to provide a motivation to combine the Warren and Nesbit references. The cited language of the Nesbit reference reads as follows:

> "As these known pastes cannot be properly sterilized, it is conventional to include 'preservatives' which include antibacterial and antiviral agents, such as alkyl p-hydroxybenzoates, in order to eradicate any bacteria or viruses that were not removed by sterilization." Emphasis added.

The Examiner utilizes the extensive list of "examples of antimicrobial agents" (see Warren et al.; column 4, line 39) to provide a citation mentioning cedar leaf oil. It is important to note that the Warren et al. reference lists well over one hundred (100) examples of antimicrobial agents. Thus, the Examiner argues that it would be obvious for one of ordinary skill in the art to add any one of the examples and, in particular, cedar leaf oil, cited as examples by Warren et al., to the teaching of the Nesbit reference for the purpose of eradicating any bacteria or viruses that were not removed by sterilization.

1a. The Examiner's rationale for combining references is not consistent with the claimed invention.

As noted above, the Examiner's rationale for combining the Nesbit and Warren et al. references may be found at column 1, lines 13-20 of the Nesbit reference which states that a preservative may be utilized to eradicate bacteria or viruses that were not removed by sterilization. In contrast, the use of cedar leaf oil by the claimed invention is as an active ingredient and not as a preservative. Specifically, the claimed invention already contains a measure of zinc oxide which is known to have antibacterial properties. (See specification, page 3, paragraph 9-10.) In short, a person of ordinary skill in the art would not be motivated to add two substances having antibacterial properties to the same solution under the rationale offered by the Examiner.

1b. The Examiner is applying an improper "obvious to try" rationale.

Applicant respectfully argues that the Examiner is applying an improper obvious to try rationale in support of the obviousness rejection, as defined by MPEP §2145. Specifically, the Examiner has provided a first reference (Nesbit) containing a general suggestion that preservatives may be used to sterilize known pastes, and a second reference (Warren et al.) containing over one hundred (100) examples that could be used as an antimicrobial agent.

Applicant respectfully argues that the Examiner, through the cited references, has suggested that one of ordinary skill in the art would read the Nesbit reference and then try each of numerous

possible choices, as listed by Warren et al., having some kind of antimicrobial properties until he or she arrived at a successful result.

Applicant respectfully submits that the prior art cited by the Examiner gives no indication whatsoever that the use of cedar leaf oil is desirable over the numerous other examples of antimicrobial agents provided by Warren et al. Further, neither reference provides any direction regarding which of the examples provided by Warren et al. is likely to be successful.

"The admonition that 'obvious to try' is not the standard under Section 103 has been directed mainly at two kinds of error. In some cases, what would have been 'obvious to try' would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful....In others, what was "obvious to try" was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it". *In re: O'Farrell*, 853 Fed.2d 894, 903, 7 USPQ2d 1673, 1681 (Fed.Cir. 1988)." (Emphasis added)

2. The references cited by the Examiner teach away from their combination.

The Applicant respectfully argues that both the Nesbit and Warren et al. references teach away from the combination proposed by the Examiner, as defined by MPEP §2145, which states that

a prior art reference "teaching away" from the invention as claimed is a significant factor to be considered in determining obviousness. In short, a prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *WL Gore & Associates, Inc. v. Garlock, Inc.*, 721 Fed.2d 1540, 220 USPQ 303 (Fed.Cir. 1983, cert. denied, 469 U.S. 851, 1984).

2a. The Nesbit reference.

As noted above, the claimed invention utilizes zinc oxide and cedar leaf oil simultaneously. However, the Nesbit reference specifically teaches away from the use of both zinc oxide and a "preservative," defined by the Examiner as cedar leaf oil, due to a resultant hyposensitivity when the solution is applied to a wound. Specifically, the Nesbit reference teaches:

1. that pastes containing zinc oxides are unstable (see Nesbit, column 1, lines 11-13);

2. use of preservatives to sterilize the unstable pastes causes hyposensitivity when applied to the wound (see Nesbit column 1, lines 18-20);

3. that the use of both a zinc oxide and "preservative" resulting in hyposensitivity is "a problem" (see Nesbit column 1, lines 21-22); and

4. that "the stable emotions of the compositions of the present invention eliminate the need for a preservative. Thus, topical zinc oxide containing compositions can be made which do not suffer from the drawback of sensitivity." (Emphasis added)

In short, Applicant respectfully argues that the Nesbit reference teaches away from the use of zinc oxide and a "preservative" as argued by the Examiner.

2b. The Warren et al. reference

Applicant respectfully directs the Board's attention to column 4, lines 30-35 of the Warren et al. reference. In this paragraph, Warren describes four (4) specific ranges in which the amount, by weight, of the antimicrobial agent would fall. These, in order, are: .001% to 5%, .01% to 2%, .05% to 1.5%, and .1% to 1.0%, being preferred.

Applicant respectfully argues that this portion of the Warren reference would lead a reader of ordinary skill in the art to believe that a decrease in the amount of antimicrobial agent from 5% to 1% would be preferred. This argument is supported by the language of the Warren reference which clearly indicates that lesser amounts of antimicrobial agent are preferred (see "preferably," "most preferably," and "more preferably" language) utilized as the percentage of antimicrobial agent is decreased.

Further, Applicant respectfully argues that the following sentence of column 4, lines 35-36, i.e., "the exact amount of antibacterial active to be used in the compositions will depend on the

particular active utilized since actives vary in potency," refers to the exact amount within the described ranges, i.e., between 1% and 5%, and teaches away from the use of these agents in amounts greater than about 5%. In light of the above, Applicant respectfully argues that the Warren et al. reference teaches away from the combination suggested by the Examiner, given that the claimed ranges of the present invention are outside of the ranges disclosed by the Warren et al. reference.

C. Claims 2-15, 17-22, 24-30, and 32-42.

Since the Section 103 rejection of independent claims 1, 16, and 31 is erroneous, the Section 103 rejection of dependent claims 2-15, 17-22, 24-30, and 32-42 is erroneous as a matter of law. *Hartness Int'l., Inc. v. Simplimatic Engr. Co.*, 819 Fed.2d 1100, 1107 (Fed. Cir. 1987); *In re: Fine*, 837, Fed.2d 1071, 1075 (Fed.Cir. 1988).

X. CONCLUSION

The Examiner's erroneous final rejection of claims 1-22 and 24-42 under 35 U.S.C. §103 must be reversed, and such action is respectfully requested.

Respectfully submitted,

Date: October 24, 2003

Robert C. Curfiss
Registration No. 26,540
Jackson Walker L.L.P.
112 East Pecan Street, Suite 2100
San Antonio, Texas 78205
Telephone: (713)752-4200
Facsimile: (713)752-4221
ATTORNEY FOR APPLICANT

APPENDIX "A"

1. A solution for the topical treatment of skin sores comprising:

cedar leaf oil comprising from about 6% to about 10% by weight;

zinc oxide ointment comprising from about 5% to about 10% by weight;

calamine lotion comprising from about 2% to about 10% by weight; and

an ointment base.

2. The solution of claim 1, wherein the calamine lotion comprises from about 2% to about 5% by weight.

3. The solution of claim 1, wherein the calamine lotion comprises about 2% by weight.

4. The solution of claim 1, wherein the calamine lotion comprises about 5% by weight

5. The solution of claim 1, wherein the cedar leaf oil comprises about 10% by weight.

6. The solution of claim 1, wherein the zinc oxide ointment comprises about 10% by weight.

7. The solution of claim 1, comprising substantially equal amounts of cedar leaf oil and zinc oxide ointment.

8. The solution of claim 1, comprising substantially equal amounts by weight of cedar leaf oil, zinc oxide ointment and calamine lotion.

9. The solution of claim 1, wherein the ointment base is selected from the list consisting of anhydrous lanolin, petroleum jelly.

10. The solution of claim 1, wherein the ointment base is comprised of about 39% by weight anhydrous lanolin and about 39% by weight of petroleum jelly.

11. The solution of claim 1, wherein the ointment base is comprised of substantially equal amounts by weight of anhydrous lanolin and petroleum jelly.

12. The solution of claim 1, further comprising from about 1% to about 2% by weight of hydrocortisone ointment.

13. The solution of claim 1, further comprising from about 1% to about 2% by weight of vitamin K.

14. The solution of claim 1, wherein the total weight of the solution is about 10 ounces.

15. The solution of claim 1, further comprising artificial food coloring.

16. A method of preparing a solution for treating skin sores comprising the step of:

combining cedar leaf oil, zinc oxide ointment, and calamine lotion with an ointment base to form a treatment ointment; said cedar leaf oil comprising between about 6% and about 10% by weight of said solution.

17. The method of preparing the solution of claim 16, wherein the cedar leaf oil is combined to comprise about 10% by weight of the treatment solution.

18. The method of preparing the solution of claim 16, wherein the zinc oxide ointment is combined to comprise from about 10% by weight of the treatment solution.

19. The method of preparing the solution of claim 16, wherein the calamine lotion is combined to comprise from about 2% to about 10% by weight of the treatment solution.

20. The method of preparing the solution of claim 16, wherein the calamine lotion is combined to comprise from about 2% to about 5% by weight of the treatment solution.

21. The method of preparing the solution of claim 16, wherein the calamine lotion is combined to comprise about 2% by weight of the treatment solution.

22. The method of preparing the solution of claim 16, wherein the calamine lotion is combined to comprise about 5% by weight of the treatment solution.

23. (Cancelled.)

24. The method of preparing the solution of claim 16, wherein the zinc oxide ointment is combined to comprise about 10% by weight of the treatment solution.

25. The method of preparing the solution of claim 16, wherein the calamine is combined to comprise about 10% by weight of the treatment solution.

26. The method of preparing the solution of claim 16, wherein the cedar leaf oil and the zinc oxide ointment are combined in substantially equal amounts.

27. The method of preparing the solution of claim 16, wherein the ointment base is selected from the list consisting of anhydrous lanolin and petroleum jelly.

28. The method of preparing the solution of claim 16, further comprising the step of combining substantially equal amounts of anhydrous lanolin and petroleum jelly to form the ointment base.

29. The method of preparing the solution of claim 16, wherein the step of combining cedar leaf oil, zinc oxide ointment, and calamine lotion with an ointment base further includes combining hydrocortizone ointment to form the treatment solution.

30. The method of preparing the solution of claim 16, wherein the step of combining cedar leaf oil, zinc oxide ointment, and calamine lotion with an ointment base. further includes combining vitamin K to form the treatment solution.

31. A method of treating skin sores comprising the step of:

applying a treatment solution to the skin sore, wherein the treatment solution comprises cedar leaf oil, zinc oxide ointment, calamine lotion and an ointment base; said cedar leaf oil comprising between about 6% and about 10% by weight of said solution.

32. The method of treating skin sores of claim 31, wherein the treatment solution is applied to a burn.

33. The method of treating skin sores of claim 31, wherein the treatment solution is applied to a diabetic skin ulcer.

34. The method of treating skin sores of claim 31, wherein the treatment solution is applied to a blister caused by Herpes Simplex 1.

35. The method of treating skin sores of claim 31, wherein the treatment solution is applied to a blister caused by Herpes Simplex 2.

36. The method of treating skin sores of claim 31, wherein the treatment solution is applied to a blister caused by Herpes Zoster.

37. The method of treating skin sores of claim 31, wherein the treatment solution is applied to an insect bite

38. The method of treating skin sores of claim 31, wherein the treatment solution is applied to a surgical incision.

39. The method of treating skin sores of claim 31, wherein the treatment solution is applied to a laceration.

40. The method of treating skin sores of claim 31, further comprising the step of periodically re-applying the treatment solution.

41. The method of treating skin sores of claim 31, further comprising the step of covering the dermal tissue with a bandage.

42. The method of treating skin sores of claim 31, wherein the treatment solution is applied to a human patient.